

	DEPARTMENT OF COMMERCE National Institute of Standards and Technology National Voluntary Laboratory Accreditation Program	ISSUE DATE: 2005-01-21
	POLICY GUIDE	NUMBER: PG-4-2005
SUBJECT: Deficiency Responses		

The purpose of this Policy Guide is to clarify existing NVLAP policy in regards to the requirements for responding to deficiencies recorded during the on-site assessment and/or those revealed during the final evaluation that leads to the accreditation decision, as defined in NIST Handbook 150, 3.4.

Resolving Deficiencies: The signature page (page 1 of 15) of the NVLAP On-Site Assessment Report (Rev. 4/01) instructs the laboratory to “respond in writing within 30 days of the date of this report, addressing all deficiencies documented by the assessor.” NIST Handbook 150, 3.2.5.2 further states: “... The response shall be signed by the Authorized Representative and include documentation that the specified deficiencies have either been corrected and/or a plan of corrective actions. A corrective action plan must include a list of actions, target completion dates, and names of persons responsible for discharging those actions.” Please note the On-Site Assessment Report also states: “All deficiencies must be satisfactorily resolved before accreditation may be granted.” For accredited laboratories, this is interpreted to mean that deficiencies adversely affecting the outcome of calibrations or tests must be addressed and corrected immediately (within the thirty days). Evidence must be supplied which clearly demonstrates that actions taken fully resolve the deficiencies, thereby removing any concern as to the quality of results of the calibrations or tests conducted by the laboratory. In those few cases where noted deficiencies do not directly affect the results of calibrations or tests, such as those related to record keeping, NVLAP may accept a plan and a schedule, as previously described, as satisfactory resolution. When this occurs, laboratories are expected to submit sufficient objective evidence demonstrating that the deficiencies have, in fact, been resolved according to the schedule. Also, please note that all responses must be sent directly to the NVLAP office, not to the assessor(s).

Referencing Deficiencies: The NVLAP On-Site Assessment Report (Rev. 4/01) states: “Each deficiency must be referenced, in your response, by item number as it is listed in the Assessment Report checklist.” It is extremely important to cite the requirement against which the deficiency is stated and, where more than one deficiency was recorded against the same requirement, either restate the specific deficiency, or indicate to which parameter the response is related. It is not necessary in most cases to restate the requirement. It is the responsibility of the Authorized Representative to understand and respond with sufficient information within the required timeframe. This will ensure that the NVLAP Program Managers and requisite technical experts can effectively and efficiently evaluate the response.

Objective Evidence: The laboratory may ask for a clarification of a deficiency either during the closing meeting or from the appropriate NVLAP Program Manager. It is required that objective evidence be submitted as proof that a deficiency has been effectively resolved. Such evidence

includes updated procedures and uncertainty analyses, corrected/updated sections of the quality documents associated with a stated deficiency, corrective action reports, etc. NVLAP reviews all responses with the assistance of technical experts as necessary. NVLAP is solely responsible for the final decision regarding the resolution of a deficiency and for the granting of accreditation.

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